

CENTURY

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PHARMACEUTICALS LTD.


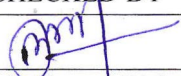
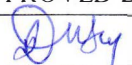
Drug Manufacturing License No: G/250 & G/513 Dt 29/1/96
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QUALITY ASSURANCE CERTIFICATE OF ANALYSIS

B. NO: 08761047-OH	NAME OF PRODUCT	A. R. NO: OH/18/047/08761
MFG DATE: August 2018	OXYTETRACYCLINE HYDROCHLORIDE BP	QUANTITY: 500.00 Kg
EXP DATE: July 2022		CAS NO: 2058-46-0
TESTING DATE: 17/08/2018		RELEASE DATE: 20/08/2018

SR. NO	TEST	SPECIFICATION	OBSERVATION
01	Characters Appearance Solubility	Yellow, crystalline powder, hygroscopic Freely soluble in water, sparingly soluble in ethanol. Solution in water becomes turbid on standing, owing to the precipitation of Oxytetracycline.	A yellow, crystalline powder; hygroscopic Complies
02	Identification	To comply the test B,C and D.	Complies
03	pH	Between 2.3 to 2.9(in 1 w/v % aqueous solution)	2.45
04	Light-Absorbing Impurities	At 430 nm: not more than 0.5 At 490 nm: not more than 0.2	0.189 0.027
05	Related Substances	Impurity A: not more than 0.5 % Impurity B: not more than 1.0 % Impurity C: not more than 2.0 % Total Impurity D,E : not more than 0.2 % Any other impurity: NMT 0.1% Total impurity: NMT 3.5%	Complies Complies Complies Complies Complies Complies
06	Water	Not more than 2.0 %	1.10 %
07	Sulphated Ash	Not more than 0.2 %	0.049 %
08	Assay	94.5 to 102.0 % $C_{22}H_{24}N_2O_9$ on anhydrous substance	99.47 %
09	Bacterial endotoxin	NMT 0.4 IU/mg of Oxytetracycline	Complies

REMARK: The product complies as per BP 2018 specifications.

	PREPARED BY	CHECKED BY	APPROVED BY
SIGNATURE			
NAME	Suhagee Darji	Maheshwari Bisht	Dr. Anand K. Dubey
DATE	20/08/2018	20/08/2018	20/08/2018